

- ii) means for analyzing the responses in order to group the individuals having a similar disease progression;
- iii) means for analyzing the responses in order to group the individuals having a similar at least a portion of the genotype; and
- iv) means for identifying the disease-influencing substance.

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#### REMARKS

In the Office Action, the Examiner noted that claims 1-29 are pending in the application and that claims 1-29 are rejected. By this amendment, independent claims 1, 10, 19, 24, and 27 have been amended. Thus, claims 1-29 are pending in the application.

#### Failure to Comply With 37 C.F.R. §§1.821-1.825

The specification has been amended to delete the exemplary sequence on page 1, lines 26-27. Accordingly, the failure to comply has been overcome.

#### Rejections Under 35 U.S.C. §112, first paragraph

Claims 1-29 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a system and methods

for identifying a disease-influencing gene, does not reasonably provide enablement for a system and method that determine a genotype of an individual and narrow the gene difference down to two categories. The Examiner claims that the invention requires undue experimentation to practice.

Based upon the newly amended independent claims 1, 10, 19, 24 and 27, Applicant respectfully disagrees with the Examiner's assertion. More particularly, amendment has been made to the independent claims which changes the scope of the claims. Applicant further disagrees with the level of experimentation needed to practice the invention, particularly in light of the amended claims.

"[A]n applicant is obliged to disclose nonclaimed elements necessary to the operation or carrying out of the invention to which the patent is directed...." However, where the invention relates only to a part of, or one aspect of, a device, an applicant is not required to disclose a nonclaimed element necessary to the operation of the overall device, but not necessary to the operation of the invention to which the patent is directed. (See *Applied Medical Resources Corporation v. United States Surgical Corporation*, 47 USPQ 2d 1289, 1291 (Fed. Cir. 1998), *cert. denied*, 142 L. Ed. 2d 772 (U.S. 1999).) Here, only "at least one physiologic characteristic relating to a genotype" or "at least a portion of the genotypes" is required pursuant to, for example, amended claims 1 and 10, respectively.

Furthermore, if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate written description requirement is met. (See *In re Alton*, 37 USPQ 2d 1578, 1584 (Fed. Cir. 1996).)

Accordingly, Applicant respectfully submits that claims 1-29 satisfy the requirements under 35 U.S.C. §112, first paragraph. Withdrawal of this rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. §103(a)**

The Examiner has rejected claims 1-29 under 35 U.S.C. §103(a) as being unpatentable over either of *Martinez; Kauffman, et al.*; or *Schork*. The Examiner claims that the difference between the studies in such references and the instant claims is the "usage of computer or automation practice by which to either gather patient information or transmit it to a central compilation facility". The Examiner has indicated that "these automatic practices only replace manual activities and are not a patentable distinction as evidenced by the legal decision of *In re Venner* (120 USPQ 192)". *In re Venner* specifically holds "It is not 'invention' to broadly provide a mechanical or automatic means to replace manual activity which has accomplished the same result".

However, Applicant's claimed invention involves much more than the replacement of manual activity with an automation practice. More particularly, see claim 1, Steps c), d), e), f), g), h), j), and k). Utilization of servers, remotely programmable apparatus, a communications network, a database, and data mining techniques in a combination that more readily allows the identification of a disease-influencing gene, as claimed in claim 1 (and other claims), is not obvious in light of *Martinez, Kauffman, et al.*, or *Schork*. Such method for identifying a disease-influencing gene is not merely the automation of manual activities. In no way is the utilization of data mining techniques the mere automation of manual activities. Particularly, neither *Martinez, Kauffman, et al.*, nor *Schork* teach the claim limitations found in any of the independent claims 1, 10, 19, 24 and 27.

Applicant does not believe that the Examiner has met the requirements for supporting an obviousness rejection. When making a rejection under 35 U.S.C. §103, there should be set forth in the Office Action: (1) the relevant teachings of the prior art relied on, ... (2) the difference or differences in the claim over the applied references, (3) the proposed modification of the applied references necessary to arrive at the claimed subject matter, and (4) an explanation why such proposed modification would have been obvious to one of ordinary skill in the art at the time the invention was made (see MPEP §706.02(j)). Accordingly,

Applicant requests the Examiner to further specify the necessary information with respect to *Martinez, Kauffman, et al.*, and *Schork*.

The Examiner's position that automated practices can be used to replace manual activities is fatally defective because it assumes the existence as prior art of Applicant's discovery. Only after reading Applicant's invention disclosure would it be obvious to program a general purpose digital computer to practice the present invention. However, 35 U.S.C. §103 requires an analysis of the prior art "at the time the invention was made to determine whether the invention was obvious". See *In re Kuehl*, 177 USPQ 250, 253 (C.C.P.A. 1973). Here, one not having knowledge of Applicant's discovery simply would not know what to program the computer to do.

Furthermore, a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. Accordingly, the "subject matter of the whole" should be considered in determining the obviousness of an invention under 35 U.S.C. §103. See *In re Nomiya*, 184 USPQ 607, 612 (C.C.P.A. 1975). Furthermore, nowhere does the prior suggest the desirability of modifying the prior art in the manner suggested by the Examiner. See *In re Debus*, Cov. App. No. 93-1320, Slip Op. at 3 ( Fed. Cir. Dec. 10, 1993) (unpublished).

Finally, the inherency of an advantage and its obviousness are entirely different questions. Just because something is inherent does not

necessarily mean it is known. Obviousness cannot be predicated on what is unknown. See *In re Spormann*, 150 USPQ 449, 452 (C.C.P.A. 1966). Here, a method for identifying a disease-influencing gene in an efficient manner as detailed in the amended independent claims is previously unknown and untaught in the prior art.

Finally, Applicant respectfully submits that claims 1-29 satisfy the requirements under 35 U.S.C. §103(a). Withdrawal of this rejection is respectfully requested.

### CONCLUSION

For all the reasons advanced above, Applicant respectfully submits that the application is in condition for allowance, and action to that end is respectfully requested. If the Examiner's next anticipated action is to be anything other than a Notice of Allowance, the undersigned respectfully requests a telephone interview before issuance of any such subsequent action.

Respectfully submitted,

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